

# **LEADING THE WAY**



## UNITED STATES ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY



FDA Antimicrobial Drugs Advisory Committee Meeting

MAJ Victor Zottig, Product Manager  
Pharmaceutical Systems Project Management Office  
26 July 2018

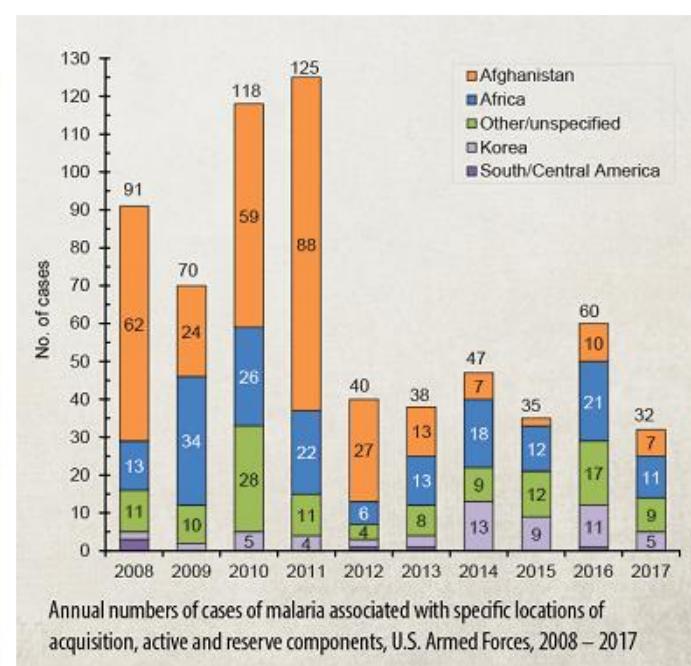
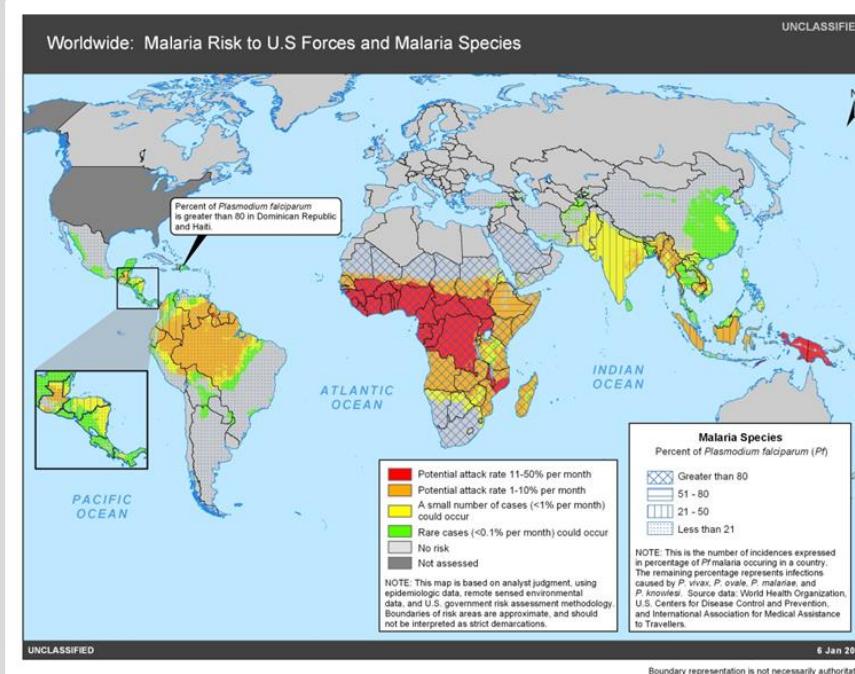
# Disclaimer

- The views expressed in the presentation are those of the author and do not necessarily represent the views of the U.S. Army or the Department of Defense (DoD).
- The author does not report any financial conflict of interest.
- Discussion of specific pharmaceutical products does not reflect an endorsement of those products. USAMMDA has a Cooperative Research and Development Agreement (statute 15 USC 3710a) and Exclusive License Agreement with 60 Degrees Pharmaceuticals for the development of Tafenoquine for Malaria Prophylaxis.

# Malaria Risks to Military Personnel

Malaria remains the number one infectious disease threat to deployed U.S. Military

- Resistance to current anti-malarial drugs is spreading
- Potential for poor chemoprophylaxis compliance with daily dosing
  - A drug with a longer half-life provides a flexible option during challenging operational conditions
- No licensed malaria vaccine
  - Lead vaccine candidates only moderately protect against only one species of malaria (*Plasmodium falciparum*)



Source: Medical Surveillance Monthly Report, Infographic; February 2018



# DoD Policy for Malaria Prophylaxis\*

Current FDA Approved Malaria Prophylactic Drug	Weekly Dosing	Effective against all disease stages?	7+ days post exposure treatment required?	Comments
<b>Doxycycline</b>	<b>No</b>	<b>No</b>	<b>Yes</b>	<ul style="list-style-type: none"> <li>✓ FDA approved; DoD first-line drug in chloroquine resistant areas</li> <li>✗ Must be taken at the same time every day</li> <li>✗ Increased photosensitivity and risk of vaginitis</li> </ul>
<b>Atovaquone - Proguanil</b>	<b>No</b>	<b>No</b>	<b>Yes</b>	<ul style="list-style-type: none"> <li>✓ FDA approved; DoD first-line drug in chloroquine resistant areas</li> <li>✗ Resistance is developing to the drug</li> </ul>
<b>Mefloquine</b>	<b>Yes</b>	<b>No</b>	<b>Yes</b>	<ul style="list-style-type: none"> <li>✓ FDA approved; for service members with intolerance or contraindications to the first-line drugs</li> <li>✗ FDA boxed warning for neuro-psychiatric adverse events</li> </ul>
<ul style="list-style-type: none"> <li>✗ <b>Chloroquine</b> - Due to widespread resistance, chloroquine is rarely used as a first line prophylaxis drug for Force Health Protection</li> <li>✗ <b>Primaquine</b> - Although listed in the CDC Yellow Book, primaquine is not FDA approved for prophylaxis and therefore not permitted for Force Health Protection</li> </ul>				

\*HA Policy 13-002; Joint Health Affairs Memorandum for the Guidance on Medications for Prophylaxis of Malaria; 15 April 2013



# Conclusion

- Malaria is debilitating and potentially fatal, and remains the top infectious disease threat to the U.S. Military
- There is an unmet medical need for a safe and effective weekly FDA approved prophylactic drug
- Current prophylactic options are insufficient
- The U.S. Army is committed to providing safe and effective solutions to protect the Warfighter